REMARKS

Status of the Claims

Pending claims

Claims 1 to 4, 6 to 22, 31, and 41 to 69 are pending.

Claims canceled and added in the instant amendment

Claims 70 to 86 are added in the instant amendment, and claims 46 to 51, 56, 59 and 60 are canceled without prejudice or disclaimer. Accordingly, after entry of the instant amendment, claims 1 to 4, 6 to 22, 31, 41 to 45, 52 to 55, 57, 58 and 61 to 86 will be pending and under consideration.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the new and amended claims. Support for methods for delivering nucleic acids to a heart can be found, inter alia, on pages 10 to 11, of the specification. Accordingly, no new matter is added in the instant amendment.

Patentably Distinct Species Requirement

In the Restriction Requirement, the Patent Office alleges that the pending claims 1, 46 to 48, 59 and 60 are generic to a plurality of disclosed patentably distinct species comprising: (i) complete or near complete cardiac arrest; and, (ii) reversible bradycardia.

It was alleged that claims 9 and 16 are generic to a plurality of disclosed patentably distinct species comprising: (i) adenoviral vector; (ii) adeno-associated viral vector.

It was alleged that claims 7 and 51 are generic to a plurality of disclosed patentably distinct species comprising: (i) histamine; (ii) substance P; and, (iii) serotonin.

It was alleged that claims 10 to 12 and 17 to 19 are generic to a plurality of disclosed patentably distinct species comprising: (i) cardiac specific promoter; (ii) CMV promoter; and, (iii) RSV promoter.

It was alleged that claims 14, 15, 21 and 22 are generic to a plurality of disclosed patentably distinct species comprising: (i) CMV enhancer; and, RSV enhancer.

It was alleged that claims 52 to 58 and 61 to 68 are generic to a plurality of disclosed patentably distinct species comprising: (i) mutated dominant negative PLB gene that enhances SERCA-2 activity; (ii) gene for treating cardiac disease; (iii) gene for treating heart failure; (iv) gene regulating cardiac contractility and relaxation; (v) gene regulating calcium handling in cardiomyocytes; (vi) gene regulating calcium uptake into sacro-endoplasmic reticulum in cardiac cell; (vii) gene encoding SERCA-2; (viii) gene encoding a polypeptide that will bind to SERCA-2; (ix) gene encoding a polypeptide that regulates SERCA-2 in cardiac cells.

The Species Election

The species requirement for claims 1, 46 to 48, 59 and 60 is moot in view of the instant amendment.

In response to the species requirement for claims 9 and 16, where the patentably distinct species allegedly comprise (i) adenoviral vector; (ii) adeno-associated viral vector, Applicants elect (ii) adeno-associated viral vector, with traverse.

In response to the species requirement for claims 7 and 51, where the patentably distinct species allegedly comprise (i) histamine; (ii) substance P; and, (iii) serotonin, Applicants elect (i) histamine, with traverse.

In response to the species requirement for claims 10 to 12 and 17 to 19, where the patentably distinct species allegedly comprise (i) cardiac specific promoter; (ii) CMV promoter; and, (iii) RSV promoter, Applicants elect (ii) CMV promoter, with traverse.

In response to the species requirement for claims 14, 15, 21 and 22, where the patentably distinct species allegedly comprise (i) CMV enhancer; and, (ii) RSV enhancer, Applicants elect (i) CMV enhancer, with traverse.

In response to the species requirement for claims 52 to 58 and 61 to 68, where the patentably distinct species allegedly comprise (i) mutated dominant negative PLB gene that enhances SERCA-2 activity; (ii) gene for treating cardiac disease; (iii) gene for treating heart failure; (iv) gene regulating cardiac contractility and relaxation; (v) gene regulating calcium handling in cardiomyocytes; (vi) gene regulating calcium uptake into sacro-endoplasmic reticulum in cardiac cell; (vii) gene encoding SERCA-2; (viii) gene encoding a polypeptide that will bind to SERCA-2; (ix) gene encoding a polypeptide that regulates SERCA-2 in cardiac cells, Applicants elect gene (ii) gene for treating cardiac disease, with traverse.

If the Patent Office withdraws the "patentably distinct species requirement," and these elected species are held to be allowable, Applicants are entitled to consideration (examination) of additional species; and if all species are held to be allowable, a generic claim should be allowed (MPEP §809.02(c); pg 800-50, 8th Edition, rev. 2, May 2004).

Reasons to reconsider and withdraw restriction requirement

Applicants respectfully request the Patent Office to reconsider and to withdraw the restriction requirement for the following reasons.

The instant invention is directed to novel methods for treating cardiac disease comprising delivering a therapeutic dose of a gene to the heart, wherein the gene comprises a mutated form of a phospholamban (PLB) gene, and the method comprises the step of administering a viral vector comprising the mutated form of the PLB gene to the heart.

Regarding the species requirement for claims 9 and 16, Applicants respectfully request the Patent Office to rejoin species (i) adenoviral vector; (ii) adeno-associated viral vector, because the invention is not limited to the use of any particular viral vector, and the patentability of the novel claimed method is not dependent on what particular viral vector is used. Furthermore, Applicants respectfully aver that after a complete search directed to the novel methods of the invention (which are not limited to use of any particular viral vector) it would not be an undue burden for the Patent Office to also do a complete search regarding making and using the methods of the invention with adenoviral vectors or adeno-associated viral vectors or any other viral vector.

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Regarding the species requirement for claims 7 and 51, Applicants respectfully request the Patent Office to rejoin species (i) histamine; (ii) substance P; and, (iii) serotonin, because the invention is not limited to the use of any particular method for efficient gene transfer, and the patentability of the novel claimed method is not dependent on whether histamine, substance P or serotonin is used. Furthermore, Applicants respectfully aver that after a complete search directed to the novel methods of the invention (which are not limited to use of histamine, substance P or serotonin) it would not be an undue burden for the Patent Office to also do a complete search regarding making and using the methods of the invention with histamine, substance P or serotonin, or any other equivalent compound.

Regarding the species requirement for claims 10 to 12 and 17 to 19, Applicants respectfully request the Patent Office to rejoin species (i) cardiac specific promoter; (ii) CMV promoter; and, (iii) RSV promoter, because the invention is not limited to the use of any particular promoter, and the patentability of the novel claimed method is not dependent on what particular promoter is used. Furthermore, Applicants respectfully aver that after a complete search directed to the novel methods of the invention (which are not limited to use of any particular promoter) it would not be an undue burden for the Patent Office to also do a complete search regarding making and using the methods of the invention with cardiac specific promoters, CMV promoters or RSV promoters or any other promoter.

Regarding the species requirement for claims 10 to 12 and 17 to 19, Applicants respectfully request the Patent Office to rejoin species (i) CMV enhancer; and, (ii) RSV enhancer, because the invention is not limited to the use of any particular enhancer, and the patentability of the novel claimed method is not dependent on what particular enhancer is used. Furthermore, Applicants respectfully aver that after a complete search directed to the novel methods of the invention (which are not limited to use of any particular enhancer) it would not be an undue burden for the Patent Office to also do a complete search directed to making and using the methods of the invention with CMV enhancers, RSV enhancers or any other enhancer.

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Regarding the species requirement for claims 10 to 12 and 17 to 19, Applicants respectfully request the Patent Office to rejoin species (i) mutated dominant negative PLB gene that enhances SERCA-2 activity to the elected species (ii) gene for treating cardiac disease, because the invention is not limited to the use of any particular mutated form of PLB for treating cardiac disease. Furthermore, Applicants respectfully aver that after a complete search directed to the novel methods of the invention (which are not limited to use of any particular mutated form of PLB) it would not be an undue burden for the Patent Office to also do a complete search directed to making and using the methods of the invention with mutated dominant negative PLB genes that enhance SERCA-2 activity. Similarly, after a complete search directed to the novel methods of the invention, it would not be an undue burden for the Patent Office to also do a complete search directed to making and using the methods of the invention using genes regulating cardiac contractility and relaxation, genes regulating calcium handling in cardiomyocytes, gene regulating calcium uptake into sacro-endoplasmic reticulum in cardiac cells, genes encoding SERCA-2; genes encoding polypeptides that will bind to SERCA-2, or genes encoding a polypeptide that regulates SERCA-2 in cardiac cells.

CONCLUSION

Applicants have set forth distinct and specific errors in the species restriction requirement and reasons for the Patent Office to reconsider and withdraw the restriction requirement. Accordingly, Applicants have preserved their right to petition the restriction to the Group Director under 37 CFR §1.144; see also MPEP §818.03(c), pg 800-60, 8th Edition, Rev. 2, May 2004.

Applicants respectfully submit that all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 220002066000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858 720 5133.

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Respectfully submitted,

By _____

Gregory P. Einhorn
Registration No.: 38,440
MORRISON & FOERSTER LLP
3811 Valley Centre Drive, Suite 500
San Diego, California 92130
(858) 720-5133

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